

III. REMARKS

This application is a continuation of application serial no. 10/134,356, filed April 27, 2002 and issued as U.S. Patent No. 6,814,702 (“the ‘702 Patent”), which is a continuation of application serial no. 09/732,274, filed December 7, 2000 and issued as U.S. Patent No. 6,428,478 (“the ‘478 Patent”), which is a divisional of application serial no. 09/315,867, filed May 20, 1999 and issued as U.S. Patent No. 6,221,021 (“the ‘021 Patent”), which is a continuation-in-part of application serial no. 08/926,209, filed September 9, 1997 and issued as U.S. Patent No. 5,947,901 (“the ‘901 Patent”).

All of the amendments made to the specification herein were made and entered by the Patent Office during the prosecution of the ‘702 Patent and the ‘021 Patent. For the convenience of the Examiner, a true and correct copy of the amendment from the prosecution history of the ‘702 Patent, corresponding to the above amendment is attached as Exhibit 1. All of the language which Applicant proposed adding by amendment herein, appears in the ‘702 Patent, as summarized in the table below.¹

Amended Paragraph	Location of Language Added In Amended Paragraph in the ‘702 Patent	Support For Amendment In Originally Filed Application
[0025]	Col 4, lines 14-22; and 27-30	Figures 2-3; Paragraphs [0011], [0016], [0017], [0025], [0034]
[0026]	Col 4, line 34	Figure 2;
[0029]	Col. 4, line 66 – Col. 5, line 1	Figure 2; Paragraphs [0011], [0016], [0017], [0025], [0029]
[0030]	Col. 5, lines 6-12	Figure 2; Paragraph [0028], [0030]
[0033]	Col. 5, lines 43-47	Figures 2-3; Paragraph [0029], [0033]
[0034]	Col. 5, line 63 – Col. 6, line 9; Col. 6, lines 17-19	Figures 2-3; Paragraphs [0011], [0016], [0017], [0034]

The right column of the above table identifies support in the originally application for the proposed amendments. The specification has been amended, as explained above. No new matter has been added. Applicant respectfully requests that these amendments be entered.

¹ A similar table appears in Exhibit 1 indicating where all of the language which Applicant proposes adding by amendment appears in the ‘021 Patent

Support for the amendment to claims 1-6 and new claims 7-13 is found in the specification, as summarized in the table below.

Amended Claim	Support in Specification for Amendment
1	Elements 22 in Figure 2
2	Elements 22 in Figure 2
3	3 knobs on ultrasonography generator in Figure 2
4	"Wave mode" knob in Figure 2
5	Paragraph [0034]
6	Paragraphs [0017], [0034]
7	Paragraph [0034]
8	Paragraphs [0035]
9	Figure 2; Paragraph [0029]
10	Figure 2; Paragraph [0033]
11	Figures 2-3; Paragraphs [0017], [0025], [0029], [0031], [0033], [0034], [0035]
12	Paragraphs [0017], [0035]
13	Figure 2; Paragraph [0025]
14	Figures 2-3; Paragraphs [0017], [0025], [0029], [0031], [0033], [0034], [0035]
15	Paragraphs [0033], [0034]
16	Figure 2; Paragraph [0029]
17	Figure 2; Paragraph [0033]

Applicant respectfully requests a Notice of Allowance of pending claims 1-17.

Respectfully submitted,

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APPENDIX

[0025] The apparatus of the present invention comprises an ultrasound generator [8] 9 and a portable housing 10 coupled to the ultrasound generator, as shown in Figure 2. As shown in Figure 2, control mechanisms for regulating the transmission of ultrasound energy from the ultrasound generator are mounted on body 9, which is sized to be grasped or held in a user's hand. In a preferred embodiment, these control mechanisms include knob-like fixtures 6-7 which may be adjusted to regulate or control the frequency or intensity of ultrasound energy emitted by the ultrasound generator. The portable housing comprises a first transducer mounting assembly 18. In a preferred embodiment, the lower transducer mounting assembly is curved. An ultrasound trigger 11 is mounted in the housing and is electrically coupled to the generator. The ultrasound trigger 11 is a triggering mechanism that can be actuated to cause ultrasound energy to be transmitted from the ultrasound source or emitters, as shown in Figures 2 and 3

[0026] In a preferred embodiment, the ultrasound generator is capable of selectively pulsed or continuous wave ultrasound energy. The selective generation may be accomplished by a control knob or switch [7] 8, as shown in Figure 2. In a preferred embodiment, the ultrasound generator further comprises frequency controls 6 and intensity controls 7, as shown in Figure 2. In a preferred embodiment, the ultrasound generator is capable of generating ultrasound energy within a frequency range of 1.8-3.5 MHz and within an intensity range of 1.0-2.0 watts/square centimeter.

[0029] The apparatus and method of the present invention may be practiced by the patient, after proper training, without assistance from another person. In the preferred embodiment shown in Figure 2, the portable housing has a pistol type grip, thereby allowing the user to operate the trigger or triggers with one hand, while manipulating the position adjuster with the other hand, as needed to maintain a suitable ultrasound coupling during penile expansion. As shown in Figure 2, the portable housing 10 is sized to be grasped or held in a user's hand. The placement of the triggers and axial position adjuster on opposite sides of the housing facilitates the user's ability to easily use both hands to simultaneously manipulate the trigger and the position adjuster.

[0030] In a preferred embodiment, the invention further comprises [an] a second transducer

mounting assembly 24 mounted across from the first transducer mounting assembly. As shown in Figure 2, the position adjuster permits the distance between housing 10 and mounting assembly 24 to be adjusted by the user using one hand. In the preferred embodiment shown in Figure 2, the mounting assembly 24 is moveably connected to the housing 10. In a preferred embodiment, the second transducer mounting assembly is mounted in alignment with the first transducer mounting assembly. In another preferred embodiment, the second transducer mounting assembly is curved. The second transducer mounting assembly is coupled to the position adjuster. In a preferred embodiment, the radii of curvature of the first and second transducer mounting assemblies are sized such that the first and second transducers can be coupled to the outer surface of a penis.

[0033] In the preferred embodiments shown in Figures 2-3, the invention further comprises an ultrasonography generator 30 connected to at least one transducer in each transducer mounting assembly and an ultrasonography trigger 12 mounted in the portable housing and connected to the ultrasonography generator. The ultrasonography trigger 12 is a triggering mechanism that can be actuated to cause ultrasound energy to be transmitted from the ultrasonography generator and through the ultrasound source or emitters, as shown in Figures 2 and 3. In a preferred embodiment the ultrasonography generator and the ultrasound generator are each connected to at least two ultrasound transducers in each of the transducer mounting assemblies. In a preferred embodiment the ultrasonography generator is a doppler ultrasound unit.

[0034] The ultrasonography generator is suitable for monitoring penile hemodynamic parameters, such as blood flow. Ultrasonographic apparatus suitable for use with the present invention are disclosed in the following U.S. Patents: 4,612,937 to Miller, and 4,334,543 to Fehr. The full disclosures of these two patents are incorporated herein by reference. In a preferred embodiment, the ultrasonography generator may comprise a display 32 for displaying measured hemodynamic parameters and/or expert system 33 capable of analyzing measured hemodynamic parameters. As shown in Figures 2 and 3, the display is located or mounted in a portable unit, such as the ultrasonography generator. As shown in Figure 2, the ultrasonography generator unit 30 is sized to be grasped or held in a user's hand. In the preferred embodiment shown in Figure 3, the system 33 is physically housed or located within the ultrasonography unit.

In the preferred embodiment shown in Figure 2, the ultrasonography generator unit comprises control mechanisms for regulating the transmission of ultrasound energy. In a preferred embodiment, these control mechanisms include rotatable knobs which may be adjusted to regulate or control the frequency, intensity or wave mode of ultrasound energy emitted by the ultrasonography generator. The expert system is capable of comparing one or more measured hemodynamic parameters to predetermined parameter limits, such as maximum blood pressure or maximum blood temperature. The expert system is further capable of generating an instruction to the user to stop ultrasound therapy if predetermined parameter limits are exceeded. These instructions may be generated via the display on the ultrasonography generator or by other visual or audible means of communication. The display of instructions stored in the expert system is an example of the ability of the display to allow the user to view stored information.



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